UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

February 27, 2013

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 1839-221, Stepan Wipe Any Hard Surface
DP Barcode: 407637

From: Marcus Rindal, Microbiologist 3.5.13
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

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Applicant: Stepan Company
22 West Frontgate Road
Northfield, IL. 60093

Formulation from the Label:

Active Ingredient(s)	% by wt.
Didecyl dimethyl ammonium chloride	0.024%
Alkyl (40% C_{12}, 50% C_{14}, 10% C_{16}) dimethyl benzyl ammonium chloride	0.016%
Other Ingredients	99.960%
Total	100.000%

I. BACKGROUND

The product, STEPAN Wipe Any Hard Surface (Reg. No. 1839-221), is an EPA-approved food contact and non-food contact sanitizer for use on hard, non-porous surfaces in industrial, institutional, and residential environments. [redacted]. The included study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Eagan, MN 55121.

This data package contained a letter from the applicant to the Agency (dated November 16, 2012), one study (MRID 489948-01), a Statement of No Data Confidentiality Claims for the study, and the proposed label.

II. USE DIRECTIONS

The product is designed for sanitizing hard, non-porous surfaces such as appliance interiors and exteriors, bathroom fixtures, bathtubs, booster chairs and seats, cabinets, car seats, carts, chairs, changing tables, computer keyboards, computers, countertops, cribs, cutting boards, desks, desktops, diaper pails, doorknobs, exercise machines, faucets, fax machines, floors, garbage cans, grocery cart handles, grocery carts, gym equipment, gymnastic equipment, headsets, high chair trays, high chairs, keyboards, railings, pet dishes and bowls, seats, shower stalls, showers, sinks, strollers, tables, tabletops, telephones, tiles, toilet seats, toilets, toys, trash cans, vanity tops, and walls. The product label indicates that the product may be used on hard, non-porous surfaces including: Formica, glazed ceramic, glazed porcelain, glazed tile, fiberglass, glass, metal (i.e., stainless steel), and plastic (e.g., acrylic, vinyl). Directions on the proposed label provided the following information regarding use of the product:

> As a sanitizer on food contact surfaces: Prior to application, remove all gross food particles and soil from surfaces that are to be sanitized. Thoroughly wash or flush the surfaces with a good detergent, followed by a potable water rinse before applying product. For lightly soiled surfaces, use a first towelette to pre-clean the surface to be treated. One standard size 7" x 8" towelette will sanitize 72 square inches of surface. Allow the surface to remain wet for 60 seconds. Let surface dry. No final potable water rinse is allowed. Use a fresh towelette for each new surface to be sanitized.
>
> As a sanitizer on non-food contact surfaces: Prior to application, remove all gross soil from surfaces that are to be sanitized. Thoroughly wash or flush the surfaces with a good detergent, followed by a potable water rinse before applying product. For lightly soiled surfaces, use a first towelette to pre-clean the surface to be treated. One standard size 7" x 8" towelette will sanitize 72 square inches of surface. Allow the surface to remain wet for 30 seconds. Let surface dry. No rinsing is required.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator,

pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces)

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution for the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v

(19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia.

IV. SUMMARY OF SUBMITTED STUDIES

1. MRID 489948-01 "Food Contact Sanitizer Test Method for Towelettes," Test Organisms: *Escherichia coli* (ATCC 11229) for Stepan Wipe Any Hard Surface, by Becky Lien. Study conducted at ATS Labs. Study completion date – October 22, 2012. Project Number A14105.

This study was conducted against *Escherichia coli* (ATCC 11229). Three lots (Lot Nos. 4060-94C-1, 4060-94A-1, and 4060-94B-1, containing 0%, 3%, and 5% IPA respectively) of the product, Stepan Wipe Any Hard Surface, were tested. The product was received ready-to-use, as a pre-saturated towelette. A culture of the challenge microorganism was prepared in accordance with the method. The culture was diluted with PBDW so that the final inoculum was 1×10^{10} CFU. Fetal bovine serum was added to the inoculum to achieve a final test culture with 5% organic soil load. Three 6" x 12" glass surfaces (i.e., carriers) per product lot were tested. Each 6" x 12" carrier was inoculated with 0.250 mL test culture. The inoculum was spread uniformly over the carrier. The carriers were dried for 40 minutes at room temperature (20.9 – 22.4°C and 27.4 – 27.5% relative humidity). One towelette was used to treat one individual carrier. Three carriers were treated per sample. The treated surface was allowed to remain exposed to the product for 30 seconds at 20°C at 31% relative humidity. The towelette was then placed into a sterile 60 mL syringe. The plunger was replaced and the liquid expressed into 100 mL of neutralizer. Following exposure, 100 mL of neutralizer was added to each carrier and the survivors were suspended using a sterile cell scraper. Ten-fold dilutions were performed and duplicate 1.0 mL aliquots of $10^0 – 10^4$ were plated for each neutralized carrier and towelette. All plates were incubated for a 48±4 hours at 35-37°C. Following incubation, the plates were enumerated and subcultures were visually examined for growth. Per the protocol, the product was also tested at a 60-second contact time. Controls included those for purity, sterility, parallel count, and neutralization effectiveness.

Inert ingredient information may be entitled to confidential treatment

V. RESULTS

Test Organism: *Escherichia coli* (ATCC 11229)					
Test Substance	Replicate	Survivors*	Total CFU (Log_{10})	% Reduction	Log_{10} Reduction
0% IPA Lot 4060-94C-1 Water Control	Carrier #1	9.9×10^{7}	1.31×10^{9} (9.12)	N/A	N/A
	Carrier #2	1.51×10^{8}			
	Carrier #3	1.37×10^{8}			
	Expressed Liquid #1	7.2×10^{8}			
	Expressed Liquid #2	8.1×10^{7}			
	Expressed Liquid #3	1.20×10^{8}			
3% IPA Lot 4060-94A-1	Carrier #1	4.1×10^{7}	1.01×10^{9} (9.00)	22.9%	0.12
	Carrier #2	3.2×10^{7}			
	Carrier #3	6.1×10^{7}			
	Expressed Liquid #1	3.9×10^{8}			
	Expressed Liquid #2	3.5×10^{8}			
	Expressed Liquid #3	1.39×10^{8}			
5% IPA Lot 4060-94B-1	Carrier #1	1.40×10^{7}	3.30×10^{8} (8.52)	74.8%	0.60
	Carrier #2	1.68×10^{7}			
	Carrier #3	2.40×10^{7}			
	Expressed Liquid #1	9.8×10^{7}			
	Expressed Liquid #2	1.29×10^{8}			
	Expressed Liquid #3	4.8×10^{7}			

*The survivors are expressed as CFU/Carrier for the carrier results and CFU/mL for the expressed liquid results.

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 489948-01) [redacted] The data demonstrate IPA, when tested with a food contact sanitizer method, produces only a 74.8% reduction in test organism over untreated controls at room temperature with a 30 second contact time. In this application, IPA alone does not satisfy the requirements to meet a food contact sanitizer claim. [redacted] Sterility controls did not show growth.

VII. RECOMMENDATIONS

[redacted]